IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Christine Carlucci and Gerard Carlucci

For: Medical Tubing Securing Device

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DECLARATION

I, Terri Lee Maurer, hereby state:

1. I am a registered nurse and have been employed at Columbia Presbyterian Hospital since 1987. I have been with the neonatal intensive care unit (NICU) at the hospital since 1989.

2. The NICU generally has around 55 newborn patients in its care at any one time. These tiny patients range in age from the smallest of "preemies" (prematurely born infants) to two or three month old infants. One of the reasons for hospitalization of many of these babies is that they require respiratory care due to such conditions as a prematurity, underdeveloped lungs, collapsible airway, small lung volume, or muscle weakness.

3. Traditional treatment for many such patients has generally been intubation which involves the insertion of tubing into the infant's nose and down into the trachea. The tubing is attached to a ventilator which pushes a volume of air into the patient's lung at regular intervals. The ventilator thus "breathes" for the patient.

4. Intubation is an invasive and uncomfortable procedure. Moreover, many problems can arise with intubation such as bronchopulmonary dysplasia and

pneumonia. For these reasons, it has been the practice of the NICU at Columbia Presbyterian to provide respiratory support to our patients using a system known as CPAP, which stands for "continuous positive airway pressure." CPAP is an airway treatment which provides a slight positive pressure of air during inhalation to increase the volume of inspired air and to decrease the work of breathing. CPAP is administered by nose.

5. The most appropriate way to administer CPAP to infants is by the use of a nasal prong apparatus. A typical example of one such commercial product for delivering infant CPAP is the Hudson RCI Infant Nasal Prong CPAP cannula system shown in the attachment **A** to this declaration. Each system includes one cannula, one inspiratory and one expiratory elbow, two 4 ft. lengths of 10 mm I.D. corrugated tubing, one 4 ft. pressure monitoring line, one 22 mm to 10 mm humidifier adapter, one knit cap, and two 5 inch sections of Velcro securing tape. Two nasal prongs, which are attached to the cannula, are inserted into the nostrils. The cannula is attached via the corrugated tubing to a pressurized line so that a positive pressure of air flows into the nostril. The tubing is kept in place by looping velcro straps around the tubing and then attaching the velcro straps to a knit hat which is placed on the infant's head.

6. While the CPAP method works well to open the alveoli, i.e., the little air sacs in the lungs, it has always been a problem to position the cannula and tubing so that the nasal prongs do not shift out of the nostrils. The knit caps which are provided with the commercial products and to which the tubing is secured with Velcro straps generally do not stay in position without extra measures. As a consequence, the nursing staff has had to resort to a number of different strategies in order to secure the

apparatus so that the nasal prongs stay in the infant's nose where they will do their work. We have tried using safety pins to anchor the tubing to the caps. We have also used rubber bands or hospital tape to secure the hats and the tubes to the infant's head.

7. These measures have not been satisfactory because they often result in skin irritation and/or discomfort, which results in the infant moving its head more and causing more irritation and discomfort and possibly, dislodging the nasal probes. Even if there is no discomfort, infants often move anyway and cause the hat to fall off the head, which then causes the tubing to pull away. As the infant gets older, the amount of movement also increases, making the older infants more prone to equipment dislocation. It has been an ongoing problem.

8. I met Christine and Gerard Carlucci when their son Anthony was a patient at the NICU unit of Columbia Presbyterian. Anthony was receiving CPAP respiratory support and was experiencing the types of problems I describe. One day Mrs. Carlucci presented us with a device that they had made and asked us if it could be used for Anthony.

9. The device was a simple elastic terrycloth headband of the type used by athletes during exercise. Mrs. Carlucci had stitched the headband together in two places, thus dividing the one large loop into three smaller loops. The center loop fit over the crown of Anthony's head and rested just above his ears. We threaded the CPAP tubing through the loops over his ears and then placed the prongs in his nose.

10. We were very happy to see how well the Carlucci band worked. Because of the elasticity of the band and the fact that it fit below the widest part of the head, the

band stayed in place and did not shift when Anthony moved. The loops held the tubing in place and there was no pulling at the nasal prongs. The softness of the terrycloth was well-tolerated, unlike the velcro straps and adhesive tape that had been used with the commercial kit.

11. I have looked at US Patent 5,411,484 to Shattuck which shows a strap which is wrapped behind a patient's neck, the ends are secured with velcro onto the strap to create loops to hold an intubation tube in place. The loops exert opposing forces on the tube to keep it centered in the patient's mouth. I have never seen such a device used for infant CPAP administration and it does not appear that it would be an appropriate device for use with infants for several reasons. First, since two nasal prongs must be kept in place, one would need to use two Shattuck straps, increasing the likelihood of irritation of sensitive skin. Second, the Shattuck straps would need to be tightened around the infant's neck in order to hold the tubes in place. As a general rule, however, we strive to avoid putting anything, especially straps, around infants' necks for safety reasons. Third, the ends of the straps are equipped with velcro which can irritate sensitive infant skin very easily. Although I see that the velcro is placed on the side of the Shattuck strap which is not meant to touch the skin, it is not unusual for medical strapping to get twisted or disconnected. If such event occurred, then the rough velcro would be in a position to irritate the skin. Moreover, if the velcro became disconnected during use, it would cause the CPAP nasal prongs to shift from effective position.

12. The Carlucci band avoids all of the problems presented by the Shattuck strap. Only one Carlucci band is needed to keep both nasal prongs in place. The

Carlucci band goes around the sturdy skull, not the vulnerable neck. The Carlucci band is fabricated of a soft, non-irritating fabric, with no sharp or rough portions. Finally, the loops of the Carlucci bands are closed and cannot be opened, so the nasal probes cannot fall away from position.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

April 7, 2005 Terri Lee Maurer RNC

Terri Lee Maurer

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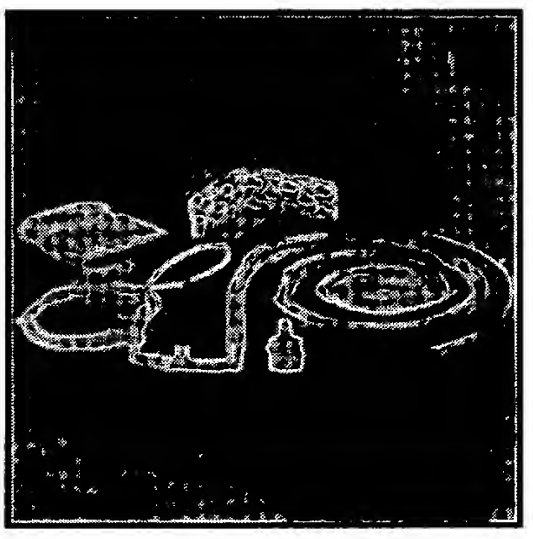
Cannulas, Masks, Tubing : Infant Nasal CPAP Cannulas

Infant Nasal Prong CPAP

The Hudson RCI infant nasal prong continuous positive airway pressure (CPAP) cannula system is designed to reduce trauma associated with the delivery of infant nasal CPAP. Hudson RCI CPAP prongs are available as a system for use with a water seal or spring loaded valve or as a set for use with any mechanical ventilator.



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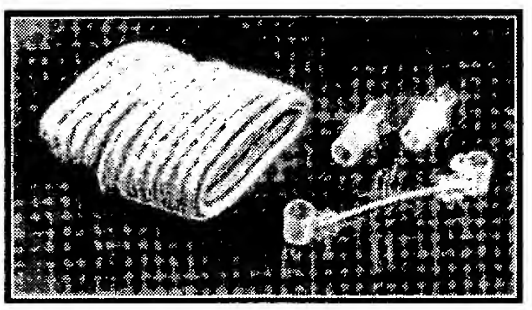
- Soft anatomically curved prongs minimize nasal septal necrosis
- Six prong sizes fit a full range of infants (see sizing chart below).
- Adjustable right-angle connector facilitates positioning of tubing to increase infant comfort
- Educational videotape available upon request
- Both systems and sets are individually packaged, 10 per case

Infant CPAP System

Each system (shown above) includes one cannula, one inspiratory and one expiratory elbow, two 4 ft. lengths of 10mm I.D. corrugated tubing, one 4 ft. pressure monitoring line, one 22mm to 10mm humidifier adapter, one knit cap and two 6 inch sections of Velcro securing tape.

Infant CPAP Sets

Sets are intended for use with mechanical ventilators and include one cannula, one inspiratory and one expiratory elbow connector, two 10mm to 7.5mm adapters, one knit cap and two 6 inch sections of Velcro securing tape (not shown in photo).



CPAP Cannula Sizing Chart & Ordering Information

Weight Range	Suggested Cannula Size	System Cat. No.	Set Cat. No
Less than 700 grams	0	1683	1690
700 grams to 1,250 grams	1	1685	1691
1,250 grams to 2,000 grams	2	1686	1692
2,000 grams to 3,000 grams	3	1687	1693

Over 3,000 grams	4	1688	1694
1 to 2 years of age	5	1689	1695

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